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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,641	02/22/2002	Patrick A. Haverkost	BSI-486US	2371

7590 01/29/2009
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EXAMINER

LANG, AMY T

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/081,641	Applicant(s) HAVERKOST ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-33,47,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 9,12-16,18-29, and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10,11,17,30-33,47 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 3-6, 10, 11, 30-33, 47, and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen Cornelius et al. (6,068,634) in view of Osborn (US 5,409,495).

With regard to **claims 1, 3, and 4**, Lorentzen Cornelius et al. (hereinafter Cornelius) discloses a stent introducer having a shaft (18) with a distal tip (28), an inner sheath (16) over the shaft, an anterograde sheath (24) attached proximally to the tip and mounted over a portion of the stent, and anchoring means (14) for anchoring the stent's proximal end after the stent has been released and expanded and which minimizes axial movement of the proximal end of the stent relative to the body lumen. The balloon is slightly expanded before the tip was moved distally to release the distal

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end of the stent could anchor the proximal end of the stent against axial movement.

The balloon could also be used to set the stent against and into the vessel wall if inflated to a high enough pressure. The inner sheath defines the inflation lumen for the balloon.

However, Cornelius does not specifically disclose the inner sheath (16), inflation lumen, as concentrically disposed under the stent.

Osborn teaches that it is well known in the art for inflation lumens to extend under the stent and balloon. Figure 3 of Osborn discloses an inflation lumen (41) that extends under the middle portion of balloon (30) (column 7, lines 47-50). Additionally, this modification involves a mere change in size which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art to merely alter the size of the inflation lumen (16) of Cornelius so that it extends to the middle portion of the balloon. This would then produce the stent mounted concentrically over the inner sheath (16).

With regard to **claims 5 and 6**, a retrograde sheath (22) extends distally over the balloon. As shown in Figure 1, the retrograde sheath is mounted concentrically over the balloon, shaft, and inner sheath.

With regard to **claims 10 and 11**, a radial spacer (27) is attached to the distal tip and provides sufficient space between the inner sheath and anterograde sheath.

With regard to **claim 30**, as shown in Figure 1, the retrograde sheath extends axially over a proximal end of the stent (20).

With regard to **claim 32**, the retrograde sheath and the anterograde sheath are laterally spaced from one another (Figure 1).

With regard to **claims 31, 33, and 51**, it is the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention to change the size of the retrograde sheath, anterograde sheath, or both. A change in size which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Therefore, one sheath would be longer than the other or both sheaths would be longer and abut or overlap each other.

With regard to **claim 47**, Osborn further teaches the advantage of utilizing three balloons (30, 33, 34) to expand the stent so that a more uniform expansion is produced (column 6, lines 57-59; column 8, lines 15-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for Cornelius to also utilize three balloons to expand the stent. Therefore, the proximal balloon (33) of Osborn would be located only under the retrograde sheath. Cornelius in view of Osborn then produces an introducer wherein a balloon (33) is mounted inside of only the retrograde sheath.

4. **Claims 7, 8, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen Cornelius et al. (6,068,634) in view of Osborn (US 5,409,495) as applied to claims 1 and 6 above, and further in view of Zadno-Azizi et al. (US 6,022,336).

Cornelius in view of Osborn discloses a stent introducer comprising a shaft, an inner sheath, and a retrograde sheath. However, neither Cornelius nor Osborn disclose a medial sheath located between the inner sheath and the retrograde sheath.

Zadno-Azizi et al. (hereinafter Zadno-Azizi) teaches that a reinforcing layer, specifically a metal braid, is well known in the art to provide increased stiffness (column 9, lines 51-59). It is the examiner's position that such a reinforcing layer overlaps the instantly claimed sheath. It is further the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention for the introducer of Cornelius in view of Osborn to comprise an additional layer of a braided metal sheath between the inner sheath and retrograde sheath to provide increased stiffness.

Since Zadno-Azizi further teaches the advantage of providing variable stiffness along the length of an introducer (column 9, lines 51-54). Variable stiffness allows the introducer be sufficiently rigid to travel through a patient's vasculature but still flexible enough to allow for quick turns through torturous anatomy. The variable Zadno-Azizi is accomplished by providing the proximal region with greater stiffness than the distal region. Therefore, it would have been obvious to one of ordinary skill in the art for the reinforcing braided sheath to terminate proximal the distal end portion of the introducer. This would produce a braided sheath that terminates proximal of the balloon.

Response to Arguments

5. Applicant's arguments filed 10/09/2008 have been fully considered but they are not persuasive.

Specifically, applicant argues that the anchoring means of Cornelius does not anchor the proximal end of the endoluminal device nor minimize relative axial movement of the endoluminal device. However, the anchoring means of Cornelius, balloon (14), lies radially underneath the endoluminal device, stent (20). The balloon is slightly expanded before the distal tip was moved distally to release the distal end of the stent could anchor the proximal end of the stent against axial movement. Basically, if the distal tip or even the distal sleeve (24) was removed, the balloon would anchor the stent until the balloon was expanded to high enough pressure. Although the distal tip is mounted to the catheter with an adhesive, it is still capable of being removed.

The balloon is also used to set the stent against the vessel wall when inflated to a high enough pressure. This would then anchor the proximal end of the stent against the vessel wall after expansion of that proximal end. Once the stent is placed against the vessel wall via the balloon, the balloon minimizes axial movement of the stent since it maintained against the vessel. While the balloon is expanded to this high pressure, the remaining distal portion of the stent is also unsheathed. Therefore, expanding the balloon to a high enough pressure to expand the stent against the vessel wall also overlaps the instant claims with regard to the anchoring means.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

01/23/2009

/Amy T Lang/

Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731